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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,281	06/22/2001	Partha S. Banerjee	18025-1013	6268

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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 05/22/2002

#7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/887,281

Applicant(s)
Banerjee et al.

Examiner
Kevin E. Weddington

Art Unit
1614



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 28, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61, 65-67, 71-73, 77-89, and 92-99 is/are pending in the application.
- 4a) Of the above, claim(s) 65-67, 71-73, 92, and 93 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-61, 77-89, and 94-99 is/are rejected.
- 7) ☒ Claim(s) 2 and 3 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1614

Claims 1-61, 65-67, 71-73, 77-89 and 92-99 are presented for examination.

Applicants' information disclosure statement filed February 11, 2002 has been received and entered.

Applicants' election filed February 28, 2002 in response to the restriction requirement of January 30, 2002 has been received and entered. The applicants elected the invention described in claims 1-62, 77-89 and 94-99 (Group I) with traverse.

Applicants' traverse of the restriction requirement is not found persuasive for reasons of record. Therefore, the restriction requirement is hereby made Final.

Claims 65-67, 71-73, 92 and 93 are withdrawn from consideration as being drawn to the non-elected invention (37 CFR 1.142(b)).

Information Disclosure Statement

The information disclosure statement filed February 11, 2002 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56© most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Art Unit: 1614

Claim Objections

Claims 2 and 3 are objected to.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Adjei et al. (E).

Adjei et al. teach a medicinal aerosol formulation comprising a particulate medicament, such as formoterol, and water (see the abstract). Clearly, the cited reference anticipates the applicants' instant invention. Therefore, the instant invention is unpatentable.

Art Unit: 1614

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-61, 77-79 and 94-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adjei et al. (E).

Adjei et al. was discussed above supra for its components for the formation of the instant invention, a pharmaceutical composition comprising formoterol and water. The reference teaches in column 2, lines 54-68, the other medicaments that can be combined with formoterol along with its suitable acid addition salts. Column 3, lines 1-3 discloses the pharmaceutically acceptable solvates, the same as the applicants.


Art Unit: 1614

The instant invention differs from the cited reference in that the cited reference does not teach the applicants' preferred amounts and concentration of each individual component that forms the instant pharmaceutical composition. However, to determine amounts and concentrations of each component to get the optimum effectiveness is well within the level of one having ordinary skill in the art, and the artisan would have been motivated to determine optimum effects of each component in the absence of evidence to the contrary.

Claims 1, 4-61, 77-89 and 94-99 are not allowed.

The remaining references listed on the enclosed PTO-892 are cited to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner K. Weddington whose telephone number is (703) 308-1235.


Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington

May 16, 2002